116TH CONGRESS 1ST SESSION	S.
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To provide better care and outcomes for Americans living with Alzheimer's disease and related dementias and their caregivers, while accelerating progress toward prevention strategies, disease modifying treatments, and, ultimately, a cure.

IN THE SENATE OF THE UNITED STATES

Mrs. Capito (for herself, Ms. Stabenow, Mr. Wicker, and Mr. Menendez) introduced the following bill; which was read twice and referred to the Committee on

A BILL

To provide better care and outcomes for Americans living with Alzheimer's disease and related dementias and their caregivers, while accelerating progress toward prevention strategies, disease modifying treatments, and, ultimately, a cure.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE; TABLE OF CONTENTS; FINDINGS.
- 4 (a) Short Title.—This Act may be cited as the
- 5 "Concentrating on High-Value Alzheimer's Needs to Get
- 6 to an End (CHANGE) Act of 2019".

2 1 (b) Table of Contents.—The table of contents for this Act is as follows: Sec. 1. Short title; table of contents; findings. Sec. 2. Cognitive impairment detection benefit in the Medicare annual wellness visit and initial preventive physical examination. Sec. 3. Medicare quality payment program. Sec. 4. Report to congress on implementation. (c) FINDINGS.—Congress finds the following: 3 4 (1) It is estimated that 5,800,000 million 5 Americans are living with Alzheimer's disease in 6 2019. This includes an estimated 5,600,000 million 7 people age 65 and older and approximately 200,000 8 individuals under age 65 who have younger-onset 9 Alzheimer's. By 2050, the number of people age 65 and older with Alzheimer's dementia is projected to 10 11 increase to 13,800,000 Americans. 12 (2) As many as half of the estimated 5,100,000 13 American seniors with Alzheimer's disease and other 14 dementias have never received a diagnosis. 15 (3) In 2019, it is expected that Alzheimer's and 16 related dementias will cost Medicare and Medicaid 17 \$195,000,000,000. By 2050, it is estimated that 18 overall Alzheimer's costs will increase to more than 19 \$1,100,000,000,000. 20 (4) Alzheimer's exacts an emotional and phys-21 ical toll on caregivers, resulting in higher incidence

of heart disease, cancer, depression, and other health

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consequences.

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(5) Alzheimer's disease disproportionately impacts women and people of color. Women are twice as likely to develop Alzheimer's as they are breast cancer. African Americans are about 2 times more likely than White Americans to have Alzheimer's disease and other dementias. Latinos are about 1½ times more likely than White Americans to have Alzheimer's disease and other dementias. According to the Centers for Disease Control, among people ages 65 and older, African Americans have the highest prevalence of Alzheimer's disease and related dementias (13.8 percent), followed by Hispanics (12.2 percent), and non-Hispanic whites (10.3 percent), American Indian and Alaska Natives (9.1 percent), and Asian and Pacific Islanders (8.4 percent). This higher prevalence translates into a higher death rate: Alzheimer's deaths increased 55 percent among all Americans between 1999 and 2014, while the number was 107 percent for Latinos and 99 percent for African Americans.

(6) The latest science reveals there are actions that can be taken both now and across the lifespan of an individual to help optimize brain health, reduce the risk of cognitive decline, and help mitigate symptoms. There are also important behavioral and social

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dimensions that could delay cognitive decline and build a resilient brain. For example, a 2016 study supported by the National Institutes of Health found that a diet high in natural plant-based foods and limited in saturated fats was associated with reduced cognitive decline. A 2017 study published by the Lancet Commission found that physical activity had a significant protective effect against cognitive decline. A study supported by the National Institutes of Health which was published in 2018 found a connection between lower blood pressure and decreased cognitive impairment. An American Academy of Neurology study recently published found that physical activity and cognitive activity were both associated with reduced risk of total dementia. (7) There are evidence-based, reliable, and National Institutes of Health-identified cognitive impairment detection tools that are available on the Alzheimer's and Dementia Resources website of the National Institute on Aging that must replace detection by direct observation in the Medicare Annual visits and Welcome to Medicare visits. The National

Institutes of Health-identified tools will allow for ap-

propriate follow-up instead of delaying diagnosis or

impeding opportunities for patients to access timely

treatment options, including clinical trial participation.

- (8) An early, documented diagnosis, communicated to the patient and caregiver, enables early access to care planning services and available medical and nonmedical treatments, and optimizes the ability of patients to build a care team, participate in support services, and enroll in clinical trials.
- (9) African Americans represent 13 percent of the United States population, but only 5 percent of clinical trial participants, and Latinos represent 17 percent of the United States population, but less than 1 percent of clinical trial participants. Further, Latinos and African Americans account for only 3.5 percent and 1.2 percent, respectively, of principal investigators supported by the National Institutes of Health funding, limiting this perspective in research. Better recruitment and trial designs are critical to addressing innovation in Alzheimer's generally, including the underrepresentation of African Americans and Latinos.
- (10) Inability to identify eligible patients at the earliest stages of disease is a substantial impediment to efficient research toward Alzheimer's disease prevention, treatment, and cure.

1	(11) Advancing treatment options to prevent
2	treat, or cure Alzheimer's is an urgent national pri-
3	ority.
4	(12) A paradigm shift to drive synergies be-
5	tween high-value patient care, caregiver support
6	brain health promotion, and research initiatives is
7	our best hope for preventing, treating, and curing
8	Alzheimer's disease.
9	SEC. 2. COGNITIVE IMPAIRMENT DETECTION BENEFIT IN
10	THE MEDICARE ANNUAL WELLNESS VISIT
11	AND INITIAL PREVENTIVE PHYSICAL EXAM
12	INATION.
13	(a) Annual Wellness Visit.—
14	(1) In general.—Section 1861(hhh)(2) of the
15	Social Security Act (42 U.S.C. 1395x(hhh)(2)) is
16	amended—
17	(A) by striking subparagraph (D) and in-
18	serting the following:
19	"(D) Detection of any cognitive impairment or
20	progression of cognitive impairment that shall—
21	"(i) be performed using a cognitive impairment
22	detection tool identified by the National Institute or
23	Aging as meeting its criteria for selecting instru-
24	ments to detect cognitive impairment in the primary

1	care setting, and other validated cognitive detection
2	tools as the Secretary determines;
3	"(ii) include documentation of the tool used for
4	detecting cognitive impairment and results of the as-
5	sessment in the medical record of the patient; and
6	"(iii) take into consideration the tool used, and
7	results of, any previously performed cognitive im-
8	pairment detection assessment.";
9	(B) by moving subparagraphs (G) and (H)
10	two ems to the left;
11	(C) by redesignating subparagraph (I) as
12	subparagraph (J); and
13	(D) by inserting after subparagraph (H)
14	the following new subparagraph:
15	"(I) Referral of patients with detected cognitive
16	impairment or potential cognitive decline to—
17	"(i) appropriate Alzheimer's disease and
18	dementia diagnostic services, including amyloid
19	positron emission tomography, and other medi-
20	cally accepted diagnostic tests that the Sec-
21	retary determines are safe and effective;
22	"(ii) specialists and other clinicians with
23	expertise in diagnosing or treating Alzheimer's
24	disease and related dementias;

1	"(iii) available community-based services,
2	including patient and caregiver counseling and
3	social support services; and
4	"(iv) appropriate clinical trials.".
5	(2) Effective date.—The amendments made
6	by paragraph (1) shall apply to annual wellness vis-
7	its furnished on or after January 1, 2020.
8	(b) Initial Preventive Physical Examina-
9	TION.—
10	(1) In general.—Section 1861(ww)(1) of the
11	Social Security Act (42 U.S.C. 1395x(ww)(1)) is
12	amended by inserting "detection of any cognitive im-
13	pairment or progression of cognitive impairment as
14	described in subparagraph (D) of subsection
15	(hhh)(2) and referrals as described in subparagraph
16	(I) of such subsection," after "upon the agreement
17	with the individual,".
18	(2) Effective date.—The amendments made
19	by paragraph (1) shall apply to initial preventive
20	physical examinations furnished on or after January
21	1, 2020.
22	SEC. 3. MEDICARE QUALITY PAYMENT PROGRAM.
23	Not later than January 1, 2020, the Secretary of
24	Health and Human Services shall implement Medicare
25	policies under title XVIII of the Social Security Act (42

1	U.S.C. 1395 et seq.), including quality measures and
2	Medicare Advantage plan rating and risk adjustment
3	mechanisms, that reflect the public health imperative of—
4	(1) promoting healthy brain lifestyle choices;
5	(2) identifying and responding to patient risk
6	factors for Alzheimer's disease and related demen-
7	tias; and
8	(3) incentivizing providers for—
9	(A) adequate and reliable cognitive impair-
10	ment detection in the primary care setting, that
11	is documented in the electronic health record of
12	the patient and communicated to the patient;
13	(B) timely Alzheimer's disease diagnosis;
14	and
15	(C) appropriate care planning services, in-
16	cluding identification of, and communication
17	with patients and caregivers regarding, the po-
18	tential for clinical trial participation.
19	SEC. 4. REPORT TO CONGRESS ON IMPLEMENTATION.
20	Not later than 3 years after the date of the enact-
21	ment of this Act, the Secretary of Health and Human
22	Services shall submit to Congress a report on the imple-
23	mentation of the provisions of, and amendments made by,
24	this Act, including—

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1	(1) the increased use of validated tools for de-
2	tection of cognitive impairment and Alzheimer's dis-
3	ease;
4	(2) utilization of Alzheimer's disease diagnostic
5	and care planning services; and
6	(3) outreach efforts in the primary care and pa-
7	tient communities.